



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/430,034 | 10/29/1999 | Frank J. Bova | 6256 | 6691 |

7590 07/12/2002

Dennis P Clarke
Miles & Stockbridge
1751 Pinnacle Drive
Suite 500
McLean, VA 22102-3833

EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT PAPER NUMBER

3737

DATE MAILED: 07/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

MAILED

JUL 12 2002

GROUP 3700

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 17

Application Number: 09/430,034
Filing Date: October 29, 1999
Appellant(s): BOVA ET AL.

Dennis P. Clark
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on 05/03/2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-23 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

Art Unit: 3737

(9) Prior Art of Record

| | | |
|-----------|---------------|---------|
| 5,682,890 | KORMOS ET AL. | 11-1997 |
| 5,370,117 | MCLAURIN | 12-1994 |
| 5,617,857 | CHADER ET AL. | 4-1997 |
| 6,122,541 | COSMAN ET AL. | 9-2000 |

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 9, 15-16, 19 and 23 have been rejected under 35 U.S.C. 102 (b) as being anticipated by Kormos et al.'890.

Regarding claims 9, 15-16, 19 and 23 Kormos et al.'890 teach a system of medical procedures, the system comprising:

a locator attachable to a patient, having at least 3 fiducial markers thereon (col. 3, lines 31-44);

a medical device for performing diagnostic imaging or a therapeutic medical procedure on a patient (col. 3, line 46-59);

a sensing subsystem for sensing the positions of the fiducial markers when the patient is in a position for performing the medical procedure using the medical device (col. 4, lines 4-27);

and

wherein the locator has a registration portion for registration with a portion of a patient's body, the locator being mechanically free such that the patient is positionable without applying forces to the locator during the patient positioning, and wherein the locator is molded to fit external features of a specific patient (col. 3, lines 3-34).

Art Unit: 3737

Claims 1-8, 10-14, 17-18, and 20-22 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Kormos et al.'890 in view of McLaurin'117.

Kormos et al.'890 teach the use of thermoplastic mesh material with markers affixed on this material, placed over the area of interest for imaging guided surgery. Kormos et al.'890 do not teach the use of this material for repeated use in imaging and therapy, and wherein the area of interest is the head/face. In the same field of endeavor, McLaurin'117 teaches the use of this material for repeated use in imaging and therapy, and wherein the area of interest is the head/face (see Abstract).

It would have been obvious to one skilled in the art at the time that the invention was made to have used the thermoplastic mesh material as taught by Kormos et al.'890 in subsequent procedures or at a later time as taught by McLaurin'117 in order to facilitate subsequent visits for treatment (see McLaurin'117 col. 2, lines 25-51). Furthermore, it would have been obvious to one skilled in the art at the time that the invention was made, to have used this thermoplastic material over the area of interest as demonstrated by both Kormos et al.'890 and McLaurin'117.

(11) Response to Argument

Appellant's arguments filed on 5/3/2002 have been fully considered, but the Examiner respectfully disagrees as to the interpretation given to the Kormos et al.'890 reference.

The Examiner's position is that the Appellant fails to recognize alternative embodiments disclosed in Kormos et al.'890. The one embodiment, as correctly recognized by Appellant, refers to the exoskeleton, which is affixed to the sides of the patient support (col. 3, lines 12-16). There is, however, an alternative embodiment, disclosed by Kormos et al.'890, one that Appellant fails to recognize. According to this embodiment, as disclosed by Kormos et al.'890,

Art Unit: 3737

the exoskeleton is a mesh of a very stiff type material, so stiff that there is no need for affixation means, and in fact it can be held in place, supported relative to itself, allowing the exoskeleton to be mechanically free (col. 3, lines 23-26; referring to the material being so stiff as to allow the tissue to be fixed relative to itself, meaning without any need for affixation means to support the exoskeleton).

This interpretation is clear when the reference is read in its totality starting from col. 3, lines 3-31. Kormos et al.'890 makes the distinction as to the different types of material used, one being flexible and stretchable in col. 3, lines 3-13, which states:

With reference to FIG. 1, a patient is received on a patient support 10. A rectangular sheet of an exoskeleton material 12 (FIG. 1A) is temporarily softened to become **flexible and stretchable**. In the preferred embodiment, the exoskeleton material is a mesh of a thermoplastic material, which softens at temperatures of about 70.degree. C. The material is held or immersed in hot water until soft. The **flexible sheet** is then removed from hot water and allowed to cool to about body temperature. The material is then stretched over and molded to the soft tissue region and **affixed by clamps or other affixing means 14** to sides of the patient support... Thereafter, the mesh material is allowed or caused to set to a relatively rigid state. (emphasis added).

Therefore, the "flexible and stretchable material" is supported by the affixation means to provide support of the material which eventually becomes rigid after cooling down, holding the tissue of interest, such as the breast, in place. Kormos et al.'890, goes on to disclose that other exoskeleton materials are contemplated (col. 3, lines 20-23) such as a plaster impregnated gauze type material, which is also affixed to a table or support. Then Kormos et al.'890 makes the clear distinction of an alternative embodiment stating: "As another alternative, the **exoskeleton material** can be a mesh of a **very stiff** but pliable elastic mesh which is **sufficiently stiff** to hold

Art Unit: 3737

the soft tissue **substantially fixed relative to itself.**" (emphasis added). In contrast with the previous sentences wherein the material used was stated to be of a flexible sheet type material or of a material type such as plaster impregnated gauze, both of which would be affixed to a table or support, here the material is stated to be of a very stiff nature holding the tissue substantially fixed relative to itself, meaning without any need for affixation means and hence allowing the very stiff exoskeleton to be mechanically free.

The selective interpretation given by the Appellant is misplaced in that there is a failure in recognizing that there are alternative embodiments using different types of materials, two of which require affixation means and yet another which can be sufficiently stiff so as to require no affixation.

The Appellant stated that the deficiency of the Kormos et al.'890, which is the primary reference is not cured via subsequent use of the secondary reference of McLaurin'117. No other arguments were presented with respect to the combination of the references or motivation to combine. Therefore, the above response by the Examiner addresses all the issues raised by the Appellant.

Art Unit: 3737

For the above reasons, it is believed that the rejections should be sustained.

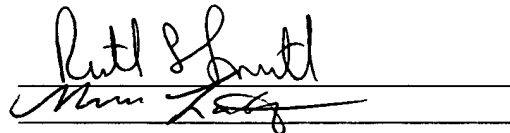
Respectfully submitted,



Eleni Mantis Mercader
July 11, 2002

Conferees

Ruth Smith, Primary Examiner of Art Unit 3737
Marvin Lateef, SPE of Art Unit 3737



DENNIS P CLARKE
MILES & STOCKBRIDGE
1751 PINNACLE DRIVE
SUITE 500
MCLEAN, VA 22102-3833